

OCT 03 2002

K 022266

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS SYNERON MEDICAL Ltd. AURORA SR

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter: Syneron Medical Ltd., Sultam Industrial park, P.O.B. 550,
Yokneam Elite 20692, Israel.

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Name of the Device: Aurora SR

Predicate Devices: The Aurora SR is substantially equivalent to a combination of the following devices: the PhotoDerm VL, manufactured by ESC Medical Systems Ltd. and subject of K950493; the PhotoDerm PL, manufactured by ESC Medical Systems Ltd. and subject of K960772; the ThermoCool, manufactured by Thermage Inc. and subject of K000944; the Vnus Closure System, manufactured by Vnus Medical Technologies Inc. and subject of K982816.

Device Description: The Aurora SR is a device that is used for treatment of superficial, benign vascular and pigmented lesions. The Aurora SR treatment is based on the principle of *selective (electromagnetic) thermolysis*. According to this principle, parameters of optical and RF energy (spectrum, exposure duration and energy density) are chosen and optimized to selectively damage pigmented and vascular lesions without damaging the surrounding tissues.

The Aurora SR is intended for use in dermatology for treatment of superficial benign vascular and pigmented lesion treatment.

Based upon an analysis of the overall performance characteristic for the device, Syneron Medical Ltd. believes that no significant differences exist. Therefore the Aurora DS should raise no new issues of safety or effectiveness.

2.7.02

Date

Amir Waldman

Dr. Amir Waldman,
Director regulatory affairs
Syneron medical Ltd.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 03 2002

Dr. Amir Waldman
Director, Regulatory Affairs
Syneron Medical, Ltd.
Sultam Industrial Park
P.O.B. 550 Yokneam Elite
20692, Israel

Re: K022266

Trade/Device Name: Aurora SR

Regulation Number: 878.4810 and 878.4400

Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology; Electrosurgical cutting and
coagulation device and accessories

Regulatory Class: II

Product Code: GEX, GEI

Dated: July 7, 2002

Received: July 12, 2002

Dear Dr. Waldman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

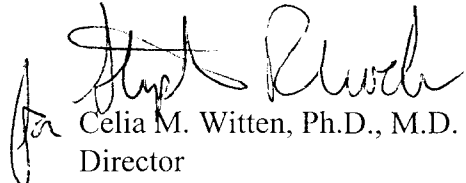
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K 022266

Device Name Aurora SR.

Indications For Use:

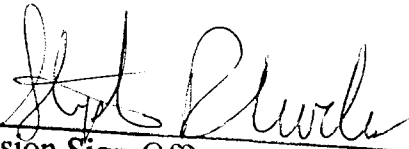
The Aurora SR is indicated for **treatment of superficial, benign vascular, and pigmented lesions.**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over The Counter Use ☐
(Per 21 CFR 801.109)

(Optional Format 1-2-96)


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022266